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Ihr Zeichen/Your Reference

Unser Zeichen/Our Reference

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Anmeldung-Nr./Application-No.

PCT/EP2004/004125

für/for

Patent

in

PCT

Anmelder/Applicant

november Aktiengesellschaft Gesellschaft für Molekulare
Medizin

Titel/Title

"DEVICE AND METHOD FOR THE PREPARATION OF ANALYTE
COMPRISING LIQUIDS"

Upon the written opinion of the International Searching Authority
dated July 19, 2004:

1. Amended Documents

Herewith

/1. amended claims 1 to 54 with marked up amendments and

/2. amended claims 1 to 54 as clean copy

are submitted, which replace pending claims 1 to 53.

Bankverbindungen
Bank accounts

Sparkasse Erlangen
Kto. Nr. 1200 4805
(BLZ 763 500 00)

HypoVereinsbank
Kto. Nr. 32 95 222
(BLZ 763 200 72)

Steuer-Nr.: 216/160/02209
Ust-IdNr.: DE229240931
Registergericht: Fürth (Bay.)
Partnerschaftsregister Nr. 025

2. Admissibility of the amendments

New claim 1 is based on former claims 1, 21, 33, page 27, lines 29 to 31 and page 28, lines 1 to 5 of the specification.

New claim 21 is based on former claim 21 and page 28, lines 1 to 5 of the specification.

New claim 22 is based on former claim 21.

New claim 33 is based on former claims 32 and 33.

The remaining claims have been renumbered. The references have been adapted.

The proposed amendments are admissible.

3. Novelty

The subject-matter of the independent claims is new vis-à-vis document D1. From document D1 it is not known to provide a material binding or adsorbing the analyte within a chamber having a reversibly changeable volume. According to the disclosure of document D1 there is provided a filter 208 within a chamber 206 (see column 17, line 63 to column 18, line 3). The volume of the chamber, in which the filter is provided cannot be reversibly changed.

According to the disclosure of document D2 there is not provided a connector which is provided with a means of flow regulation, and is connected to the channel or one of the chambers for loading of a sample solution into the first or the second chamber. According to the content of document D2 the sample solution is introduced into the chambers through an open mouth 31 at the top of the chamber (see column 3, lines 20 to 25 and column 6, lines 61 to 63). The subject-matter of the independent claims is new vis-à-vis the disclosure of document D2.

According to document D3 there is provided a system for nucleic acid analysis. Therein the analyte is bound in a capillary, which is not provided within a chamber having a changeable volume.

The subject-matter of the independent claims is new vis-à-vis the disclosure of document D3.

In the device described in document D4 there is not provided any means for binding or adsorbing an analyte. The device of document D5 does not comprise a connector which is connected to the channel or one of the chambers for loading of a sample solution into the first or second chamber.

The chambers disclosed in document D6 do not have a reversibly changeable volume. Consequently the subject-matter of the new independent claims is novel vis-à-vis documents D3 to D6.

4. Inventive step

Document D1 is considered to represent the nearest coming prior art.

Therein there is disclosed a device for contamination free preparation of analyte containing sample solution, comprising

a first and a second chamber, which are connected by a channel,

wherein the first chamber has means for reversibly changing its volume, and the second chamber has a reversibly changeable volume and

wherein a connector, which is provided with a means of flow regulation, is connected to the channel or one of the chambers for loading of a sample solution into the first or second chamber.

It is not known from document D1 that in at least one of the chambers a material binding or adsorbing the analyte is provided, the material

i) coating at least a part of a surface or the chamber

or

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New claim 22 is based on former claim 21.

New claim 33 is based on former claims 32 and 33.

The remaining claims have been renumbered. The references have been adapted.

The proposed amendments are admissible.

3. Novelty

The subject-matter of the independent claims is new vis-à-vis document D1. From document D1 it is not known to provide a material binding or adsorbing the analyte within a chamber having a reversibly changeable volume. According to the disclosure of document D1 there is provided a filter 208 within a chamber 206 (see column 17, line 63 to column 18, line 3). The volume of the chamber, in which the filter is provided cannot be reversibly changed.

According to the disclosure of document D2 there is not provided a connector which is provided with a means of flow regulation, and is connected to the channel or one of the chambers for loading of a sample solution into the first or the second chamber. According to the content of document D2 the sample solution is introduced into the chambers through an open mouth 31 at the top of the chamber (see column 3, lines 20 to 25 and column 6, lines 61 to 63). The subject-matter of the independent claims is new vis-à-vis the disclosure of document D2.

According to document D3 there is provided a system for nucleic acid analysis. Therein the analyte is bound in a capillary, which is not provided within a chamber having a changeable volume.

The subject-matter of the independent claims is new vis-à-vis the disclosure of document D3.

In the device described in document D4 there is not provided any means for binding or adsorbing an analyte. The device of document D5 does not comprise a connector which is connected to the channel or one of the chambers for loading of a sample solution into the first or second chamber.

The chambers disclosed in document D6 do not have a reversibly changeable volume. Consequently the subject-matter of the new independent claims is novel vis-à-vis documents D3 to D6.

4. Inventive step

Document D1 is considered to represent the nearest coming prior art.

Therein there is disclosed a device for contamination free preparation of analyte containing sample solution, comprising

a first and a second chamber, which are connected by a channel,

wherein the first chamber has means for reversibly changing its volume, and the second chamber has a reversibly changeable volume and

wherein a connector, which is provided with a means of flow regulation, is connected to the channel or one of the chambers for loading of a sample solution into the first or second chamber.

It is not known from document D1 that in at least one of the chambers a material binding or adsorbing the analyte is provided, the material

i) coating at least a part of a surface or the chamber

or

- ii) being provided in the chamber in form of freely in the sample solution moveable beads.

The proposed device is simple to manufacture and allows a reliable and automated preparation of an analyte like a nucleic acid.

An object of the present invention is to provide a device and a method allowing a reliable and automated preparation of an analyte.

The solution of this object is not obvious from document D1. According to the disclosure of document D1 there is provided for the binding or adsorbing of the analyte a conventional filter. According to column 18, lines 1 to 3

the filter may be made of nylon or polypropylene with pore size of about 0,45 microns ...

Such a filter can easily clog. The proposed device is not suitable for an automated preparation of an analyte. The subject-matter of new claim 1 is not obvious from document D1.

The same argument is valid for document D2. Document D2 teaches at column 4, lines 48 to 59 the use of a conventional filter through which the liquid sample is urged (see column 4, lines 58 and 59). By urging a liquid sample through a conventional filter there is created an undesirable overpressure which may negatively influence accuracy of the preparation of the analyte. As outlined above the filter proposed in document D2 may clog. In this case an automated preparation of the analyte is no longer possible. The subject-matter of new claim 1 is not obvious from a combination of document D2 with document D1.

Document D3 teaches the use of a capillary for binding or adsorbing the analyte. Neither from document D1 nor from document D3 it is known to provide the material binding or adsorbing the analyte within a chamber having a reversibly changeable volume. Having knowledge about the teaching of document D3 the skilled person would not be motivated to provide the capillary described therein within a chamber having a reversibly changeable volume because in this case one has to await that

the capillary would brake. The subject-matter of new claim 1 is not obvious taking into account the disclosure of document D3.

The device disclosed in document D4 does not have a material binding or adsorbing an analyte. The same argument is valid for document D5. The subject-matter of new claim 1 is not obvious in combination with one of the documents D4 or D5.

From document D6 there is known a diagnostic device, the interior surfaces of one or more fluid passages or chambers thereof may themselves be derivatised to provide functional groups appropriate for the desired purification. However, from document D6 it is not known to provide the material binding or adsorbing the analyte within a chamber the volume of which is reversibly changeable.

According to the teaching of document D1 there is provided a separate chamber in which a filter material is taken up. The volume of this separate chamber is not changeable. Similar to that according to the teaching of document D6 there is also provided a chamber without a changeable volume in which an binding or adsorbing material is contained. When combining the teachings of document D1 with D6 the skilled person would not be motivated to provide the material binding or adsorbing the analyte within a chamber having a changeable volume. Consequently the subject-matter of amended claim 1 is to be considered to involve an inventive step.

Amended claim 34 being directed to a method contains the limiting feature of "using a device according to any one of claims 1 to 33". As the device itself is new and inventive over the prior art also the method using said device is new and inventive with respect to the prior art.

It is respectfully submitted that the amended claims 1 to 54 are patentable. It is requested to submit an International Preliminary Examination Report indicating the patentability of the present subject-matter.

By auxiliary request it is requested to conduct a personal interview in accordance with Rule 66.6 PCT.


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